

CLAIMS:

1. An isolated BPC-1 protein having the amino acid sequence as shown in FIG. 1, from amino acid residue number 1 through amino acid residue 158.

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2. An isolated BPC-1 protein having the amino acid sequence as shown in FIG. 1, from amino acid residue number 24 through amino acid residue 158.

10 3. An isolated protein comprising at least one CUB domain of the BPC-1 protein as shown in FIG. 1, from about amino acid residue number 51 through about amino acid residue number 152.

15 4. An isolated polypeptide of at least 15 contiguous amino acids of the protein of claim 1.

5. An isolated polypeptide which is at least 90% identical to the amino acid sequence of the protein of claim 2 over its entire length.

20 6. An isolated polynucleotide selected from the group consisting of (a) a polynucleotide having the sequence as shown in FIG. 1, wherein T can also be U; (b) a polynucleotide having the sequence as shown in FIG. 1, from nucleotide residue number 793 through nucleotide residue number 1269, wherein T can also be U; (c) a polynucleotide having the sequence as shown in FIG. 1, from nucleotide residue number 862 through nucleotide residue number 1269, wherein T can also be U (d) a polynucleotide encoding a BPC-1 polypeptide whose sequence is encoded by the cDNA contained in plasmid p19P1E8 clone 6.1 as deposited with American Type Culture Collection as Accession No. 98833; (e) a polynucleotide encoding the BPC-1 protein of claim 1; (f) a polynucleotide encoding the BPC-1 protein of claim 2; and (g) a polynucleotide encoding the BPC-1 protein of claim 3.

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7. An isolated polynucleotide comprising the precursor BPC-1 coding sequence as shown in FIG. 1 from nucleotide residue number 793 through 1269.

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8. An isolated polynucleotide comprising the mature BPC-1 coding sequence as shown in FIG. 1 from nucleotide residue number 862 through 1269.

9. An isolated polynucleotide comprising the BPC-1 CUB domain coding sequence as shown in FIG. 1 from nucleotide residue number 943 through 1248.

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10. An isolated polynucleotide which is fully complementary to a polynucleotide according to claim 6.
 11. A recombinant expression vector which contains a polynucleotide according to
5 claim 6.
 12. A host cell which contains an expression vector according to claim 11.
 13. An isolated polynucleotide according to claim 6 which is labeled with a detectable
10 marker.
 14. A process for producing a BPC-1 protein comprising culturing a host cell of claim
12 under conditions sufficient for the production of the polypeptide and recovering
the BPC-1 protein from the culture.
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 15. The process according to claim 14 wherein the BPC-1 protein is secreted into the
culture medium.
 16. A BPC-1 polypeptide produced by the process of claim 14 or 15.
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 17. An antibody which immunospecifically binds to the BPC-1 protein of claim 1.
 18. An antibody which immunospecifically binds to the BPC-1 protein of claim 2.
 - 25 19. An antibody which immunospecifically binds to the BPC-1 protein of claim 3.
 20. An antibody which immunospecifically binds to the polypeptide of claim 4.
 21. A monoclonal antibody according to claim 17, 18, 19 or 20.
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 22. A monoclonal antibody according to claim 21 which is labeled with a detectable
marker.
 23. A monoclonal antibody according to claim 22, wherein the detectable marker is
35 selected from the group consisting of a radioisotope, fluorescent compound,
bioluminescent compound, chemiluminescent compound, metal chelator or
enzyme.

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24. An Fab, F(ab')2, Fv or Sfv fragment of a monoclonal antibody according to claim 17, 18, 19 or 20.
 25. A fragment of a monoclonal antibody according to claim 24 which is labeled with a detectable marker.
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 26. A fragment of a monoclonal antibody according to claim 25, wherein the detectable marker is selected from the group consisting of a radioisotope, fluorescent compound, bioluminescent compound, chemiluminescent compound, metal chelator or enzyme.
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 27. A monoclonal antibody according to claim 17, 18, 19 or 20 which comprises murine antigen binding region residues and human antibody residues.
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 28. A monoclonal antibody according to claim 17, 18, 19 or 20 which is a human antibody.
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 29. A transgenic animal producing a monoclonal antibody according to claim 28.
 30. A hybridoma producing a monoclonal antibody according to claim 21.
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 31. A recombinant protein comprising the antigen binding region of a monoclonal antibody according to claim 17, 18, 19 or 20.
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 32. A recombinant protein according to claim 31 which is labeled with a detectable marker.
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 33. A recombinant protein according to claim 32, wherein the detectable marker is selected from the group consisting of a radioisotope, fluorescent compound, bioluminescent compound, chemiluminescent compound, metal chelator or enzyme.
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 34. A single chain monoclonal antibody which comprises the variable domains of the heavy and light chains of a monoclonal antibody according to claim 17, 18, 19 or 20.
 35. A vector comprising a polynucleotide encoding a single chain monoclonal antibody according to claim 34.

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36. A monoclonal antibody according to claim 17, 18, 19 or 20 which inhibits the growth of tumor cells which express BPC-1 in a patient treated with an effective amount of said antibody.
- 5 37. A bi-specific monoclonal antibody which binds to two epitopes within the mature BPC-1 protein.
38. An assay for detecting the presence of a BPC-1 protein in a biological sample comprising contacting the sample with an antibody of claim 22, an antibody fragment of claim 25, or a recombinant protein of claim 32, and detecting the binding of BPC-1 protein in the sample thereto.
- 10 39. The assay of claim 38, wherein the biological sample is serum.
- 15 40. The assay of claim 38, wherein the biological sample is semen.
41. The assay of claim 38, wherein the biological sample is urine.
- 20 42. An assay for detecting the presence of a BPC-1 polynucleotide in a biological sample, comprising
- 25 (a) contacting the sample with a polynucleotide probe which specifically hybridizes to the BPC-1 cDNA contained within plasmid p19P1E8 clone 6.1 as deposited with American Type Culture Collection as Accession No. 98833, or the polynucleotide as shown in FIG. 1, or the complements thereof; and
- 30 (b) detecting the presence of a hybridization complex formed by the hybridization of the probe with BPC-1 polynucleotide in the sample, wherein the presence of the hybridization complex indicates the presence of BPC-1 polynucleotide within the sample.
43. An assay for detecting the presence of BPC-1 mRNA in a biological sample comprising:
- 35 (a) producing cDNA from the sample by reverse transcription using at least one primer;
- (b) amplifying the cDNA so produced using BPC-1 polynucleotides as sense and antisense primers to amplify BPC -1 cDNAs therein;

- (c) detecting the presence of the amplified BPC -1 cDNA,
5 wherein the BPC -1 polynucleotides used as the sense and antisense probes are capable of amplifying the polynucleotide shown in FIG. 1.
44. A method of detecting the presence of a cancer expressing BPC-1 protein in an individual which comprises detecting BPC-1 protein present in the serum of the individual using an assay according to claim 38.
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45. The method according to claim 44 which further comprises quantifying and comparing the amount of BPC-1 protein present in a test serum sample of the individual with the amount of BPC-1 protein present in a comparable serum sample of a normal individual, the presence of a higher amount of BPC-1 protein in the test serum sample relative to the normal serum sample indicating the presence of a cancer expressing BPC-1 protein.
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46. The method according to claim 44 or 45, wherein the cancer is prostate cancer.
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47. The method according to claim 44 or 45, wherein the cancer is bladder cancer.
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48. A method of detecting the presence of a bladder cancer expressing BPC-1 protein in an individual which comprises detecting BPC-1 protein present in the urine of the individual using an assay according to claim 38.
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49. A method of detecting the presence of a cancer expressing BPC-1 protein which comprises determining the level of BPC-1 protein expressed by cells in a test tissue sample from an individual, or in a serum, semen or urine sample from an individual, and comparing the level so determined to the level of BPC-1 expressed in a corresponding normal sample, the presence of elevated BPC-1 protein in the test sample relative to the normal sample providing an indication of the presence of such cancer in the individual.
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50. A method of diagnosing the presence of cancer in an individual comprising:
(a) obtaining a test sample of tissue from the individual;
(b) determining the level of BPC-1 mRNA expressed in the test sample;

(c) comparing the level so determined to the level of BPC-1 mRNA expressed in a comparable known normal tissue sample,

the presence of elevated BPC-1 mRNA expression in the test sample relative to the normal tissue sample providing an indication of the presence of cancer.

51. The method of claim 50, wherein the cancer is prostate cancer, and the test and normal tissue samples are selected from the group consisting of prostate tissue, bone tissue, lymphatic tissue, serum, blood or semen.
 52. The method of claim 50, wherein the cancer is bladder cancer, and the test and normal tissue samples are selected from the group consisting of bladder tissue, lymphatic tissue, serum, blood, semen or urine.
 53. A method of diagnosing the presence of cancer in an individual comprising:
 - (a) obtaining a test sample of tissue from the individual;
 - (b) determining the level of BPC-1 protein expressed in the test sample;
 - (c) comparing the level so determined to the level of BPC-1 protein expressed in a comparable known normal tissue sample,
the presence of elevated BPC-1 protein in the test sample relative to the normal tissue sample providing an indication of the presence of cancer.
 54. The method of claim 53, wherein the cancer is prostate cancer, and the test and normal tissue samples are selected from the group consisting of prostate tissue, lymphatic tissue, bone tissue, serum, blood or semen.
 55. The method of claim 53, wherein the cancer is bladder cancer, and the test and normal tissue samples are selected from the group consisting of bladder tissue, lymphatic tissue, serum, blood, semen or urine.
 56. A method of treating a patient susceptible to or having a cancer that expresses BPC-1 which comprises administering to said patient an antibody according to claim 18 or 19 in an amount sufficient to inhibit the function of BPC-1.

57. The method according to claim 56, wherein the cancer is selected from the group consisting of prostate cancer and bladder cancer.
- 5 58. A method of treating a patient with a cancer that expresses BPC-1 which comprises administering to said patient a vector according to claim 35, such that the vector delivers the single chain monoclonal antibody coding sequence to the cancer cells and the encoded single chain antibody is expressed intracellularly therein.
- 10 59. The method according to claim 58, wherein the cancer is selected from the group consisting of prostate cancer and bladder cancer.
60. A method of treating a patient with a cancer that expresses BPC-1 which comprises inhibiting the transcription of BPC-1 in the cells of said cancer.
- 15 61. The method according to claim 60, wherein BPC-1 transcription is inhibited by contacting the BPC-1 gene with an antisense polynucleotide complementary to a polynucleotide of claim 6.
- 20 62. A method of treating a patient with a cancer that expresses BPC-1 which comprises inhibiting the translation of BPC-1 mRNA in the cells of said cancer.
63. The method according to claim 62, wherein BPC-1 mRNA translation is inhibited by contacting the BPC-1 mRNA with an antisense polynucleotide complementary to a polynucleotide of claim 6.
- 25 64. The method according to claim 62, wherein BPC-1 mRNA translation is inhibited by contacting the BPC-1 mRNA with an antisense polynucleotide complementary to the 5' UTR of the BPC-1 mRNA.
- 30 65. The method according to claim 62, wherein BPC-1 mRNA translation is inhibited by contacting the BPC-1 mRNA with a ribozyme capable of cleaving said BPC-1 mRNA.
66. A method of treating a patient with a cancer that expresses BPC-1 which comprises inhibiting the processing of BPC-1 in the cells of said cancer.
- 35 67. A method of treating a patient with a cancer that expresses BPC-1 which comprises inhibiting the secretion of BPC-1 from the cells of said cancer.

68. The method according to claim 66, further comprising administering chemotherapy or radiation therapy to the patient.
- 5 69. A vaccine composition for the treatment of a cancer expressing BPC-1 comprising an immunogenic portion of a BPC-1 protein according to claim 2 and a physiologically acceptable carrier.
- 10 70. A vaccine composition for the treatment of cancer expressing BPC-1 comprising a polypeptide encoding an immunogenic portion of a BPC-1 protein according to claim 2 and a physiologically acceptable carrier.
71. A method of inhibiting the development of a cancer expressing BPC-1 in a patient, comprising administering to the patient an effective amount of the vaccine composition of claim 78 or 79.

PCT/EP2008/002350